Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AIDS DRUG ASSISTANCE PROGRAM COST CONTAINMENT STRATEGIES

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EXECUTIVE SUMMARY

PURPOSE

Compare the prices that State AIDS Drug Assistance Programs are paying for drugs to the Federal ceiling prices listed in the Federal Supply Schedule.

BACKGROUND

The Ryan White Comprehensive AIDS Resource Emergency (CARE) Act requires that a portion of Title II State grants are allocated to establish AIDS Drug Assistance Programs (ADAPs). The ADAPs provide medications to low-income individuals living with HIV/AIDS who have limited or no coverage from private insurance or Medicaid. Overall, Federal contributions have risen dramatically from the original appropriation of $52 million in fiscal year (FY) 1996 to $528 million in the FY 2000 budget.

The ADAPs are facing fiscal challenges from increasing demand due to growing numbers of low-income people living with HIV and the increased cost of drug treatments due to a changing standard of care. The Public Health Service treatment guidelines recommend combination antiretroviral therapies that typically range between $10,000 and $12,000 a year per client. In this environment, cost containment has emerged as a key means to address the issue of client access.

One of the principle methods ADAPs have to contain drug costs is the 340B Drug Pricing Program. This program provides drug price ceilings to ADAPs that purchase their drugs through a central purchaser as well as certain other federally funded entities. This program also provides a rebate option for ADAPs who do not have a central purchaser.

The Drug Pricing Program was enacted by Section 602 of the Veterans Health Care Act of 1992. Section 603 of the same law mandated minimum drug discounts for four large Federal agencies, known as the Big 4. Section 603 prices, known as the Federal ceiling prices, are available to the specified agencies through the Federal Supply Schedule. The ceiling price calculations stipulated in Section 602 and 603 are not equivalent.

FINDINGS

ADAP ceiling prices are, on average, 16 percent higher than the Federal ceiling prices

The ceiling prices limiting drug expenditures for ADAPs are, on average, 16 percent higher than the Federal ceiling prices limiting drug costs for the Big 4. As a result,

ADAPs will pay an average of 29 cents more per pill and 32 dollars more per bottle than the Big 4 agencies pay for the same drug.

ADAPs could have saved nearly $58 million in 1999 if allowed to purchase the 10 drugs at Federal ceiling prices

Comparing the actual per drug expenditures of the ADAPs to what they would have paid if they had access to Federal ceiling prices results in $57.5 million in Federal savings for ADAPs in 1999. Considering expenditures from all sources of funding, ADAPs could have saved $72 million given access to Federal ceiling prices. The $57.5 million in Federal savings could have been used to purchase additional life-saving pharmaceuticals to meet the therapeutic needs of several thousand more individuals living with HIV/AIDS.

When broken out by the type of Drug Pricing Program participation, direct purchase States (22 ADAPs) would save $14.4 million given access to Federal ceiling prices, and rebate States (22 ADAPs) would save $39 million. For the five States not participating in the Drug Pricing Program, the savings equal $4 million, bringing the total to $57.5 million in Federal savings.

RECOMMENDATIONS

The Health Resources and Services Administration (HRSA) should seek legislation to change the 340B ceiling price calculation to the Federal ceiling price calculation

As indicated in our findings, making this calculation change would result in $57.5 million in annual Federal savings for ADAPs. Also, although it was not in the scope of our study to provide a precise estimate regarding the savings available to all 340B Drug Pricing Program eligible entities, a 16 percent reduction in the ceiling price for pharmaceuticals could save these entities $240 million in Federal funds.

While this represents significant programmatic savings, 340B drug expenditures in total only represent one percent of the domestic pharmaceutical market. The Big 4 agencies, already covered under Section 603, represent just another one and a half percent of the market. Given the limited scope of the proposed changes, it seems likely that any pharmaceutical industry loss due to lower Federal prices to 340B eligible entities could be regained in additional sales volume. At the time this study was conducted, 11 ADAPs had waiting lists while the demand for combination therapies of two or three drugs continues to accelerate. A potential benefit for the manufacturers is a simplified, uniform Federal pricing system to track and report, with price-changing data submissions and recalculations required only once a year.

Even though the Big 4 and ADAPs would access the same Federal ceiling prices for outpatient covered drugs, we recommend that the programs stay discrete. The prime vendor could negotiate contracts below the 603 ceiling prices for the 340B entities similar to the way the VA negotiates multi-year contracts for users of the Federal Supply Schedule.

To allow ADAPs to negotiate the lowest prices possible, HRSA should seek legislation to exempt all sales to 340B covered entities from the calculation of Non-Federal Average Manufacturers Price

We recommend that HRSA seek to add exclusionary language to the statutes codifying the 340B Drug Pricing Program (42 USC 256B) stating that any price negotiated below the 340B statutory ceiling price would be excluded from the calculation of the non-Federal Average Manufacturer Price. Currently, sales *at* the 340B ceiling price are excluded from this calculation, but sales *below* the ceiling are considered commercial sales by the VA and are included. Defining sales below the ceiling prices as commercial sales lowers average commercial prices. This also lowers the Big 4, Federal ceiling prices since they are a percentage of average commercial prices. The linkage between these two pricing schedules creates a disincentive for manufacturers to offer below 340B ceiling prices since these have the potential to reduce Federal ceiling prices. The Prime Vendor cannot successfully negotiate prices lower than the 340B ceiling, currently, or lower than the Federal ceiling, potentially, until this is changed.

HRSA should continue to work with rebate and non-participating ADAPs to devise ways to grant them access to up-front drug discounts

Currently, ADAPs that utilize a multiple contract pharmacy model for the purchase and distribution of pharmaceuticals are not eligible to access the 340B Drug Pricing Program ceiling prices. The ADAPs using this model would also not be able to take advantage of any savings gained by obtaining Federal ceiling prices. In light of this, we recommend that HRSA continue to work with rebate and non-participating ADAPs to devise ways to grant them access to direct purchase pricing discounts.

AGENCY COMMENTS

The HRSA concurred with the report's findings and recommendations. They also offered suggestions for clarifying the report and making other technical changes. We appreciate their suggestions and, where appropriate, we changed the report to reflect their comments. The complete text of HRSA comments can be found in Appendix C. Further, staff from the office of the Assistant Secretary of Planning and Evaluation (ASPE) expressed concerns regarding our first recommendation.

The concern raised by ASPE staff has to do with the larger policy implications of our first recommendation. In particular, they are concerned that allowing 340B entities to utilize the Section 603 Federal ceiling price might affect the ability of the VA and the Big 4 to maintain the low prices they currently obtain. We understand their concern about the negotiations. In fact, it was our concern with this very issue that lead us to recommend that 340B pricing be linked to the statutorily defined Federal ceiling price as opposed to the negotiated Federal Supply Schedule (FSS) contract prices the VA and the Big 4 actually pay for drugs. The Federal ceiling price acts only as an upper ceiling to the FSS prices. In reality, the VA uses its considerable volume to negotiate prices below the Federal ceiling. Allowing 340B entities to utilize the same ceiling calculation as the VA and the Big 4 merely provides them with an equitable starting point. Discussions with the VA confirmed that this is a realistic recommendation in consideration of larger policy implications.